

whom the data and information are referred. The Food and Drug Administration will determine whether information submitted will be treated as confidential in accordance with the provisions of Part 20 of this chapter.

[45 FR 7484, Feb. 1, 1980]

§ 809.5 Exemption from batch certification requirements for in vitro antibiotic susceptibility devices subject to section 507 of the act.

(a) Antibiotic susceptibility devices subject to section 507 of the act are exempt from the batch certification requirements of Part 431 of this chapter if the following conditions are met:

(1) The antibiotic susceptibility device is approved for marketing under an appropriate antibiotic application.

(2) The antibiotic susceptibility device is packaged and labeled for dispensing in accordance with the applicable regulation (monograph) in this chapter except where other labeling has been approved in an applicable antibiotic application.

(3) The bulk antibiotic drug used in preparing the antibiotic susceptibility device meets the standards of identity, strength, quality, and purity specified in the applicable regulation (monograph) in this chapter except where other standards have been approved in an applicable antibiotic application.

(4) The antibiotic susceptibility device meets the standards of identity, strength, quality, and purity specified in the applicable regulation (monograph) in this chapter except where other standards have been approved in an applicable antibiotic application.

(b) For each antibiotic susceptibility device subject to an exemption under this section, an approved antibiotic application is regarded to be an approved premarket approval application under section 515 of the act.

(c) Nothing in this section prevents a manufacturer from applying for batch certification of an antibiotic susceptibility device as provided in section 507(c) of the act.

(d) All exemptions from batch certification requirements for antibiotic susceptibility devices under this section

are subject to the conditions of effectiveness under § 809.6.

[47 FR 39160, Sept. 7, 1982, as amended at 53 FR 11252, Apr. 6, 1988]

§ 809.6 Conditions on the effectiveness of exemptions of antibiotic susceptibility devices from batch certification requirements.

(a) If at any time after an exemption from batch certification requirements for an antibiotic susceptibility device has been granted, the Commissioner finds on the basis of new information before the agency with respect to such exempted device evaluated together with the evidence available to the agency when such exemption was granted, that certification of each batch is necessary to ensure its safety and efficacy of use, the Commissioner shall act immediately to revoke all exemptions from batch certification requirements granted for such device.

(b) If the Commissioner finds that the person granted an exemption from batch certification requirements for an antibiotic susceptibility device has failed to comply with the requirements of section 507 of the act and the regulations promulgated thereunder; or if the Commissioner finds that the requirements of § 809.5 have not been met; or if the Commissioner finds that the petition for exemption from batch certification contains any false statements of fact, the Commissioner may revoke the exemption from batch certification requirements immediately and require batch certification of the device until such person shows adequate cause why the exemption from batch certification requirements should be reinstated.

(c) If the Commissioner repeals or suspends an exemption from batch certification requirements for an antibiotic susceptibility device, a notice to that effect and the reasons therefor will be published in the FEDERAL REGISTER.

(d) Any person who contests the revocation or suspension or denial of reinstatement of an exemption from batch certification requirements for an antibiotic susceptibility device shall have an opportunity for a regulatory hearing before the Food and Drug Administration under Part 16 of this chapter.

[47 FR 39160, Sept. 7, 1982]

Subpart B—Labeling**§ 809.10 Labeling for in vitro diagnostic products.**

(a) The label for an in vitro diagnostic product shall state the following information, except where such information is not applicable, or as otherwise specified in a standard for a particular product class. Section 201(k) of the act provides that “a requirement made by or under authority of this act that any word, statement, or other information appear on the label shall not be considered to be complied with unless such word, statement, or other information also appears on the outside container or wrapper, if any there be, of the retail package of such article, or is easily legible through the outside container or wrapper.”

(1) The proprietary name and established name (common or usual name), if any.

(2) The intended use or uses of the product.

(3) For a reagent, a declaration of the established name (common or usual name), if any, and quantity, proportion or concentration of each reactive ingredient; and for a reagent derived from biological material, the source and a measure of its activity. The quantity, proportion, concentration, or activity shall be stated in the system generally used and recognized by the intended user, e.g., metric, international units, etc.

(4) A statement of warnings or precautions for users as established in the regulations contained in 16 CFR Part 1500 and any other warnings appropriate to the hazard presented by the product; and a statement “For In Vitro Diagnostic Use” and any other limiting statements appropriate to the intended use of the product.

(5) For a reagent, appropriate storage instructions adequate to protect the stability of the product. When applicable, these instructions shall include such information as conditions of temperature, light, humidity, and other pertinent factors. For products requiring manipulation, such as reconstitution and/or mixing before use, appropriate storage instructions shall be provided for the reconstituted or mixed product which is to be stored in the

original container. The basis for such instructions shall be determined by reliable, meaningful, and specific test methods such as those described in § 211.166 of this chapter.

(6) For a reagent, a means by which the user may be assured that the product meets appropriate standards of identity, strength, quality and purity at the time of use. This shall be provided, both for the product as provided and for any resultant reconstituted or mixed product, by including on the label one or more of the following:

(i) An expiration date based upon the stated storage instructions.

(ii) A statement of an observable indication of an alteration of the product, e.g., turbidity, color change, precipitate, beyond its appropriate standards.

(iii) Instructions for a simple method by which the user can reasonably determine that the product meets its appropriate standards.

(7) For a reagent, a declaration of the net quantity of contents, expressed in terms of weight or volume, numerical count, or any combination of these or other terms which accurately reflect the contents of the package. The use of metric designations is encouraged, wherever appropriate. If more than a single determination may be performed using the product, any statement of the number of tests shall be consistent with instructions for use and amount of material provided.

(8) Name and place of business of manufacturer, packer, or distributor.

(9) A lot or control number, identified as such, from which it is possible to determine the complete manufacturing history of the product.

(i) If it is a multiple unit product, the lot or control number shall permit tracing the identity of the individual units.

(ii) For an instrument, the lot or control number shall permit tracing the identity of all functional subassemblies.

(iii) For multiple unit products which require the use of included units together as a system, all units should bear the same lot or control number, if appropriate, or other suitable uniform identification should be used.